

SUPPORT FOR THE AMENDMENT

Support for the amendments to claims 12 and 22 is found in claim 17 as previously presented and in paragraphs [0037] and [0042] of the specification. No new matter would be added to this application by entry of this amendment.

Upon entry of applicants' amendment, claims 1-12, 14, 16, 18-23, 26 and 28-29 will now be active in this application with claims 12, 14, 16, 18-19, 22, 23, 26 and 28-29 being under active consideration.

REQUEST FOR RECONSIDERATION

The claimed invention is directed to a process for producing a low-caffeine green tea extract.

Green tea has received considerable interest as a source of catechins and the recognized physiological effects of catechins. Due to otherwise low catechin concentrations in green tea, concentrated extracts have been prepared which can increase the availability of catechins. However, tea leaves also contain caffeine, a compound which can have adverse effects, especially when consumed in large quantities. While decaffeinating procedures have been developed, issues as to color deterioration can be observed. Accordingly, methods for preparing low-caffeine green tea extracts are sought.

The claimed invention addresses this problem by providing a low-caffeine green tea producing process having a high concentration of non-polymer catechins which comprises contacting a green tea extract with a combination of an organic solvent comprising ethanol and water in a ratio of 91-97/3-9, activated carbon, 2.5-25 wt. parts of acid clay or activated clay, wherein a ratio of activated carbon to acid clay or activated clay is from 1 to 10. Applicants have discovered the combination of activated carbon with acid clay and/or activated clay and combination of organic solvent and water to provide for effective selective caffeine reduction without significantly deteriorating the color. Such a process is nowhere disclosed or suggested in the cited art of record.

As evidence of an enhancement in caffeine removal while retaining a high concentration of non-polymer catechins, resulting from the combination of activated carbon and active clay and/or acid clay when extracted with an organic solvent comprising ethanol and water in a ratio of 91/9 to 97/3, applicants submit herewith the declaration of Mr. Hitoshi Sato, a researcher for Kao Corporation, the assignee of the above-identified application.

Mr. Sato tested additional process examples using the high and low end of the organic solvent comprising ethanol to water ratio, the upper and lower limits of the acid clay content and a process using activated clay. For the examiner's convenience, a portion of the data is reproduced below, along with example 1 and comparative example 1 from the above-identified application.

	Example 1 in the present application	Additional Example 1	Additional Example 2	Additional Example 3	Additional Example 4	Additional Example 5	Comparative Example 1 in the present specification
Solid green tea extract (g) (POLYPHENON HG product of Tokyo Food Techno CO.,Ltd)		Ethanol 91%	Ethanol 97%	Acid clay lower limit	Acid clay upper limit	Activated clay	
Ethanol (g)	200	200	200	200	200	200	100
Water (g)	760	728	776	760	760	760	-
Solvent comprising ethanol and water (g)							
Activated Carbon (g) (KURARAYCOAL GLC product of Kuraray Chemical K.K.)	20	20	20	20	20	20	-
Acid Clay (g) (MIZUKA ACE#600, product of Mizusawa Chemical Industries, Ltd.)	100	100	100	20	200	-	100
Activated clay (g) (GalleonEarth V2R, product of Mizusawa Chemical Industries, Ltd.)	-	-	-	-	-	100	-
Organic solvent / Water (weight ratio)	95/5	91/9	97/3	95/5	95/5	95/5	-
Acid clay or activated clay in solvent (wt%)	12.5%	12.5%	12.5%	2.5%	25.0%	12.5%	11.1%
Acid clay or activated clay : activated carbon (weight ratio)	5:1	5:1	1:1	10:1	5:1	5:1	-
Non-polymer catechins / caffeine after treatment (weight ratio)	33.0	39.6	45.7	25.4	195.3	25.6	23.6

Gallocatechins percentage of non-polymer catechins after treatment (wt %)	<b>51.0</b>	<b>52.2</b>	<b>51.2</b>	<b>50.9</b>	<b>51.9</b>	<b>51.5</b>	<b>49.6</b>
Gallocatechins percentage of non-polymer catechins after treatment (wt %)	<b>74.9</b>	<b>77.3</b>	<b>77.0</b>	<b>76.5</b>	<b>77.6</b>	<b>76.8</b>	<b>75.8</b>
Concentration of non-polymer catechins in solid after treatment (wt %)	<b>66</b>	<b>63</b>	<b>69</b>	<b>68</b>	<b>71</b>	<b>72</b>	<b>34</b>
Absorbance (-)	<b>0.038</b>	<b>0.043</b>	<b>0.030</b>	<b>0.040</b>	<b>0.025</b>	<b>0.035</b>	<b>0.535</b>
Assessment of purified products	Caffeine content was lowered, color was good, and stability was visually good.	Caffeine content was lowered, color was good, and stability was visually good.	Caffeine content was lowered, color was good, and stability was visually good.	Caffeine content was lowered, color was good, and stability was visually good.	Caffeine content was lowered, color was good, and stability was visually good.	Caffeine content was lowered, color was good, and stability was visually good.	Color deteriorated and precipitation occurred.

Additional examples 1 and 2 demonstrate high non-polymer catechin concentrations after treatment, a reduced caffeine content and good color and stability using ratios of organic solvent to water of 91/9 (additional example 1) and 97/3 (additional example 2), the endpoints of the claimed range. Additional examples 3 and 4 demonstrate high non-polymer catechin concentrations after treatment, a reduced caffeine content and good color and stability using amounts of acid clay of only 2.5% (additional example 3) and 25% (additional example 4), the endpoints of the claimed content of acid clay. Additional example 5 demonstrates high non-polymer catechin concentrations after treatment, a reduced caffeine content and good color and stability using an activated clay. This performance is offered in contrast to comparative example 1 in which only water was used as the solvent.

Applicants have previously submitted evidence of an enhancement in caffeine removal in the Ueoka declaration submitted April 22, 2010. A portion of the data is reproduced below:

	Example 1 in the present application	Additional comparative Example 1	Additional comparative Example 2	Additional comparative Example 3	Additional comparative Example 4
Solid green tea extract(g) (POLYPHENON HG product of Tokyo Food Techno CO., Ltd)	200	200	200	200	200
Ethanol (g)	760	560	760	760	760
Water(g)	40	240	40	40	40
Activated Carbon (g) (KURARAYCOAL GLC product of Kuraray Chemical K.K.)	20	20	0	0	20
Acid Clay (g) (MIZUKA ACE#600, product of Mizusawa Chemical Industries, Ltd.	100	100	100	120	0
Organic solvent / Water (weight ratio)	95/5	70/30	95/5	95/5	95/5
Non-polymer catechins / caffeine after treatment (weight ratio)	33.0	35.9	16.4	20.4	18.5
Gallates percentage of non-polymer catechins after treatment (wt %)	51.0	52.4	52.4	52.7	49.6
Gallocatechins percentage of non-polymer catechins after treatment (wt %)	74.9	78.8	77.2	77.2	77.1
Concentration of non-polymer catechins in solid after treatment (wt %)	66	49	61	63	64
Absorbance (-)	0.038	0.058	0.098	0.099	0.018

Assessment of purified products		Color deteriorated and concentration of non-polymer catechins in solid after treatment was lowered.	Caffeine content was not lowered and color deteriorated.	Caffeine content was not lowered and color deteriorated.	Caffeine content was not lowered and color not lowered.
Caffeine content was lowered, color was good, and stability was visually good.					

Additional comparative examples 2, 3 and 4 demonstrate the degree of caffeine removal and color stability when using only one of activated carbon or acid clay. In each case, **a reduction in the caffeine content was not detected** using either adsorbent alone. Additional comparative examples 2 and 3 also had color deterioration. Further, as demonstrated in additional comparative example 1, using a mixture of only 70 wt. % ethanol in water and a combination of activated carbon and acid clay, even though the caffeine content was lowered, a substantial reduction in the non-polymer catechins in the solids after treatment was also observed.

In contrast, using a combination of activated carbon and acid clay and mixture of 95 wt. % ethanol in water, the caffeine content was reduced, the concentration of non-polymer catechins in solid after treatment remained high, and the color was good and stability was visually good. Thus, by using the combination of activated carbon and acid clay or activated clay, with a mixture of 91-97 wt. % of organic solvent in water, applicants are able to reduce the caffeine content, keep the catechin content high and maintain a good color.

Such results are not suggested by Funahashi et al. alone, as neither the use of activate carbon nor the use of 91-97 wt. % organic solvent in water are disclosed. Such enhancements to a caffeine removal process could therefore not have been suggested.

The rejections of claims 12, 16, 17 and 22 under 35 U.S.C. §103(a) over Funahashi et al. JP 2000-166466 in view of Hall, Jr. et al. U.S. 4,229,612, Katz U.S. 4,324,840 Klima et al. U.S. 4976979 and in further view of Bailey et al. U.S. 6,210,679, of claim 14 under 35 U.S.C. §103(a) in further view of Tsai et al. U.S. 4,935,256, of claims 18 under 35 U.S.C. §103(a) in further view of Clausi et al. EP 0167399, Wolnzach DE 3414767 and Wang CN 1141727, of claim 19 under 35 U.S.C. §103(a) in further view of Yumoto et al. JP 10-004919, Tsai et al. U.S. 4946701 and Niino et al. U.S. 2003/0185950, of claim 23 under 35 U.S.C. §103(a) in further view of Nakamura et al. JP 06-142405, of claim 26 under 35 U.S.C.

§103(a) in further view of Kuraray coal as evidenced by Okamoto et al. U.S. 4,026,795 and Inagaki et al. U.S. 5,393,329, of claim 27 under 35 U.S.C. §103(a) in further view Wang et al. CN 1141727, of claim 28 under 35 U.S.C. §103(a) in further view of Hatano et al. EP 1120379, and of claim 29 under 35 U.S.C. §103(a) in further view of in further view of Nakaura et al. JP 06-141405 are respectfully traversed.

None of the cited art of record disclose or suggests an enhancement in caffeine removal using a combination of activated carbon and acid clay or activated clay and a solvent comprising 91-97 wt. % organic solvent in water.

Funahashi et al. describes preparation of an antimicrobial agent for pickled food in which **tea leaves are primarily extracted** with water or acidic water and then the **tea leaves are further extracted** with at least one of water, ethanol, acetone, aqueous ethanol and aqueous acetone (abstract). Paragraph [0033] has been cited for disclosing treatment of the tea extract with a known clay adsorbent for the removal of caffeine. However, there is no disclosure of using the combination of activated carbon and acid clay or activated clay (page 5 of official action of November 30, 2009).

*Funahashi et al. Fails to Describe Contacting A Green Tea Extract A Combination of Adsorbents of Active Carbon And Activated Clay or Acid Clay*

Paragraph [0033] of Funahashi et al. has been cited for disclosing caffeine removal from a tea extract. Only a magnesium silicate is described. A mixed adsorbent of activated carbon and 2.5 to 25 weight parts of acid clay or activated clay is not disclosed.

Even though Katz discloses that clay and activated carbon have been used as solid adsorbents in the decaffination of liquids (column 1, line 51 through column 2, line 2), there is no disclosure of using **the combination** of activated carbon with an acid clay or activated clay and as such **an enhanced removal of caffeine can not be suggested.**

Applicants have provided evidence above, that a combination of activated carbon with an acid clay or activated clay provides for an enhancement in caffeine removal.

While page 12 of the outstanding official action questions whether it is unexpected to have an enhanced caffeine removal by using two materials known to remove caffeine, applicants note that additional example 3 used a total of 40 g of two adsorbents while additional comparative example 2 used 100 g of the single adsorbent of acid clay. None the less, additional example 3 was more effective at caffeine removal as evidenced by a higher ratio of non-polymer catechins /caffeine (25.4 v. 16.4), a higher concentration of non-polymer catechins (68 v. 61) and a lower absorbance (0.040 v. 0.098).

Applicants also note that example 1 used a total of 120 g of two adsorbents while additional comparative example 3 used 120 g of the single adsorbent of acid clay. None the less, example 1 was more effective at caffeine removal as evidenced by a higher ratio of non-polymer catechins/caffeine (33.0 v. 20.4), a higher concentration of non-polymer catechins (66 v. 63) and a lower absorbance (0.038 v. 0.099). Thus, the combination of activated carbon with an acid clay or activated clay is demonstrated to be more effective at removal of caffeine while retaining a high concentration of non-polymer catechin, such removal being achieved using a lower total amount of adsorbent. A higher content of non-polymer catechins is not suggested by using the claimed combination of adsorbents.

Further, while page 12 asserts that removal of caffeine would be expected to provide for a lower degree of coloration due to a recognized color complex formed with caffeine, the examiner's attention is directed to additional comparative examples 3 and 4 submitted in the declaration of Mr. Hideaki Ueoka on April 22, 2010.

Additional comparative examples 3 and 4 has similar concentrations of non-polymer catechins (63-64), yet additional comparative example 4 had a much lower ratio of non-polymer catechins/caffeine (20.4 v. 18.5). Thus, additional comparative example 4 clearly

has a greater caffeine content than that of additional comparative example 3. However, additional comparative example 4 had a lower absorbance of only 0.018 v an absorbance of 0.099 for additional comparative example 3. Thus, analysis of additional comparative examples 3 and 4 provides **evidence** that the concentration of caffeine is not directly proportional to the degree of coloration such that the examiner's speculation as to a reduced caffeine content providing an expectation of a reduced degree of coloration is rebutted. Further applicants note that the passage of Niino et al. relied upon by the examiner (paragraph [0006]) identifies a complex formed with oxidized polyphenol with caffeine, proteins, pectin or polysaccharides, catalyzed by metal ions to form a complex. Thus, the examiner's interpretation as to the expectation of a reduced coloration due to a decrease in caffeine content is not supported by the disclosure. Since coloration is principally a result of an oxidized polyphenol complex, the concentration of caffeine is not demonstrated to be proportional to coloration.

Moreover, while page 12 asserts that the claimed ratio of organic solvent to water of 91/9 to 97/3 is conventional to remove caffeine from green tea, such an assertion is simply not supported by the evidence in the references.

Bailey et al. discloses at column 3, lines 47-56 the use of 95% aq ethanol to desorb **catechins** from a catechin specific adsorbent. A crude extract is loaded onto a column containing a catechin specific adsorbent and the catechins are desorbed using 95% aq ethanol. The caffeine is separated from the catechins by selective adsorption of catechins to the adsorbent. Thereafter, the catechins are removed from the adsorbent using 95% aq ethanol. The aq ethanol is not present during the separation of catechins from caffeine.

Wang et al describes extraction of caffeine from **tea leaves** from super critical CO<sub>2</sub> to which fluids such as N<sub>2</sub>, Ar, ethyl alcohol, methyl alcohol, acetone, ethyl alcohol acetate may

be added (see abstract). Thus, aq ethanol is not conventionally used to adsorb caffeine onto an adsorbent of activated carbon an acid clay and/or activated clay.

Clearly the assertion that the claimed aq ethanol is conventionally used, in a process of adsorbing caffeine onto an adsorbent, is not supported by the disclosures cited. Since ht adsorbent treatment in Funahashi et al. is form the removal of caffeine, the conditions of the secondary references which do not remove caffeine is most certainly relevant to the motivation to combine the disclosures.

Further paragraph 18 on page 13 of the official action makes note that the examples of Funahashi et al. report the contacting of a green tea, solvent and activated clay on a filter paper. Examples 6, 7 and 9 describes processes in which tea leaves are extracted with 300 mL of ethanol 40% at room temperature for 1 h then covered with 15 g of magnesium silicate or activated clay, then filtered and dried. There is no disclosure of an ethanol/ water ratio of 91/9 to 97/3. 40% ethanol as used in the reference is not within the claimed ratio.

Paragraph 19 on page 13 of the outstanding office action has noted that each of additional comparative examples 1-4 in the declaration of Mr. Hideaki Ueoka of April 22, 2010, produce compositions having a non-polymer catechin contents within the claimed range of 25-90 wt.%. The relevancy of this observation by the examiner is truly vexing. Each of additional comparative examples 1-4 from the Ueoka declaration are comparative because the process used in each of the example fails in at least one way to meet all of the claim limitations therein claimed. Specifically, additional comparative example 1 is comparative because the ratio of organic solvent to water of only 70/30 is below the claimed minimum of 91/9. Additional comparative examples 2 and 3 are comparative because activated carbon is not used. Activated carbon is a claim limitation. Additional comparative example 4 is comparative because neither an acid clay nor an activated clay are used. Acid

clay and/or activated clay is a claim limitation. Thus, each of additional comparative examples 1-4 from the Ueoka declaration are clearly comparative.

Moreover, in spite of the level of non-polymer catechins remaining in each of additional comparative examples 1-4, each of the comparative examples was inferior in term of at least color quality and caffeine content. Thus, in spite of the non-polymer catechin content, the additional comparative examples were less suitable due to differences in the color or caffeine content.

The basic deficiencies of the primary reference are not cured by any of the secondary references.

Hall, Jr. et al. has been cited for evidence that magnesium silicate is a clay adsorbent. Applicants note that applicants' specification identifies on page 16 acid clay and activated clay as containing, as general chemical components SiO<sub>2</sub>, Al<sub>2</sub>O<sub>3</sub>, Fe<sub>2</sub>O<sub>3</sub>, CaO, MgO, etc. but does not identify all clays which contain MgO and SiO<sub>2</sub> as acid clays or activated clays. Thus, some activated clays contain MgO and SiO<sub>2</sub>, but not all MgO and SiO<sub>2</sub> containing compositions are activated clays. Thus, Hall, Jr. et al., fails to provide evidence that Funahashi et al. disclose use of an acid clay. None the less, Hall, Jr. et al. fails to suggest any enhancement in caffeine removal by using a combination of activated carbon with acid clay or activated clay and the claimed combination of organic solvent and water.

Katz has been cited for disclosing the use of a combination of activated carbon and clay for removing caffeine, citing to claim 8. Applicants note that claim 8 only identifies activated carbon and clay as **equivalent solid caffeine adsorbents** but fails to identify either of **acid clay or activated clay**, nor an enhancement in caffeine removal by using both activated carbon and acid clay or activated clay with the combination of organic solvent comprising ethanol and water, as claimed.

Bailey et al. has been cited for a disclosure of extraction techniques to obtain green tea extract using 95% ethanol. Applicants note that the cited disclosure describes the **desorption of catechins** from an adsorbent to which catechins have been specifically adsorbed. Using 95% ethanol **to desorb catechins** from an adsorbent fails to suggest such using 95% aqueous ethanol in the **adsorption of caffeine** on to an adsorbent. Moreover, the reference fails to suggest an enhancement in caffeine removal by using both activated carbon and acid clay or activated clay with the combination of organic solvent and water, as claimed.

Tsai et al. has been asserted as disclosing the convention concept of dissolving dry green tea extract in an organic solvent prior to further extraction. Applicants note that Tsai et al. describe **the extraction of flavanol compounds** from natural sources in which flavanols are extracted into hot water, green and grassy flavors are removed by extraction with hexane and alcohol followed by isolation of flavanols by extraction of the aqueous phase into ethyl acetate (column 2, lines 6-17). Thus, while dissolution of dry green tea extract may be conventional in the isolation of flavanols **by liquid extraction**, such does not suggest dissolving green tea extract in an organic solvent and water for treatment with a solid adsorbent.

Nakamura et al. has been cited as disclosing the use of an acid clay for removing caffeine from an aqueous solution but fails to disclose the combination of acid clay with activated carbon and therefore can not suggest an enhancement in caffeine removal from the combination using the combination of organic solvent and water, as claimed.

In view of the deficiencies of the cited art to disclose or suggest an enhancement in caffeine removal from the combination of activated carbon and acid clay or activated clay, using the combination of organic solvent and water, as claimed, the claimed invention would not have been obvious over the cited combination of references and accordingly, withdrawal of the rejections under 35 U.S.C. §103(a) is respectively requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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